UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 5, 2020 (May 5, 2020)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road Tarrytown, New York 10591-6707

(Address of Principal Executive Offices, including zip code)

(914) 847-7000

Registrant's telephone number, including area code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 **Results of Operations and Financial Condition.**

On May 5, 2020, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2020. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information included or incorporated in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release, dated May 5, 2020, Reporting First Quarter 2020 Financial and Operating Results.

104 Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 5, 2020

REGENERON PHARMACEUTICALS, INC.

By:	/s/ Joseph J. LaRosa
Name:	Joseph J. LaRosa
Title:	Executive Vice President, General Counsel and Secretary

REGENERON
Press Release

Regeneron Reports First Quarter 2020 Financial and Operating Results

- *First quarter 2020 revenues increased 33% to $1.83 billion versus first quarter 2019[4]*
- *First quarter EYLEA® U.S. net sales increased 9% to $1.17 billion versus first quarter 2019*
- *First quarter Dupixent® global net sales[2], which are recorded by Sanofi, increased 129% to $855 million versus first quarter 2019*
- *First quarter 2020 GAAP diluted EPS was $5.43 and non-GAAP diluted EPS[1] was $6.60*
- *Libtayo® Phase 3 trial in first-line non-small cell lung cancer stopped early due to positive overall survival benefit with regulatory submissions planned later this year*
- *Libtayo showed clinically-meaningful and durable responses in pivotal second-line advanced basal cell carcinoma trial with regulatory submissions planned later this year*
- *Novel SARS-CoV-2 antibody "cocktail" treatment advancing rapidly; clinical studies planned for June 2020*
- *Praluent restructuring agreements with Sanofi finalized*

Tarrytown, New York (May 5, 2020) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2020 and provided a business update.

"Over 30 years, the Regeneron team has built a science and technology engine uniquely suited to address the COVID-19 pandemic and we are applying our signature passion, innovation, and drive to advance solutions. Our novel antibody cocktail, REGN-COV2, which is specifically-designed for both prevention and treatment, is expected to begin human studies in June and we are working in parallel to have large-scale quantities available by late summer," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Beyond our COVID-19 efforts, we maintain our commitment to the many other patients with serious diseases who are counting on us. In the first quarter, we saw continued growth with EYLEA, Dupixent, and Libtayo in the U.S. driven by underlying demand despite the impact of the pandemic. Moreover, we continue to advance our broad immuno-oncology platform, including the PD-1 inhibitor Libtayo, for which we plan regulatory submissions this year in both non-small cell lung cancer and basal cell carcinoma, based on recent promising late-stage results."

"We believe our recent revision to the accounting presentation better reflects the nature of revenues earned and costs incurred and simplifies our financial reporting," said Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron. "We were also pleased to close the Praluent restructuring transaction with Sanofi, which we expect to be accretive beginning in the second quarter of 2020."

Financial Highlights

($ in millions, except per share data)	Q1 2020	Q1 2019	% Change
Total revenues[4]	$ 1,828	$ 1,373	33%
GAAP net income	$ 625	$ 461	36%
GAAP net income per share - diluted	$ 5.43	$ 3.99	36%
Non-GAAP net income[1]	$ 771	$ 518	49%
Non-GAAP net income per share - diluted[1]	$ 6.60	$ 4.45	48%

Business Highlights

Key Pipeline Progress

Regeneron has more than 20 product candidates in clinical development, including five marketed products for which it is investigating additional indications. Updates from the clinical pipeline include:

EYLEA® (aflibercept) Injection

- In February 2020, the Company announced positive two-year results from the Phase 3 PANORAMA trial evaluating EYLEA in patients with moderately severe to severe non-proliferative diabetic retinopathy (NPDR). The two-year data demonstrated that EYLEA reduced the likelihood of developing vision-threatening events by at least 75% in patients with NPDR.
- In March 2020, the Ministry of Health, Labour and Welfare (MHLW) approved EYLEA for the treatment of neovascular glaucoma (NVG) in Japan.

Dupixent® (dupilumab)

- The U.S. Food and Drug Administration (FDA) accepted for priority review the supplemental Biologics License Application (sBLA) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis, with a target action date of May 26, 2020. In addition, a Marketing Authorization Application (MAA) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis has also been submitted in the European Union (EU).
- In March 2020, the MHLW approved Dupixent for chronic rhinosinusitis with nasal polyposis (CRSwNP) in Japan.
- The sBLA for the 300 mg auto-injector is under review by the FDA, with a target action date of June 20, 2020.

Oncology Program

- In April 2020, the Company and Sanofi announced that the primary endpoint was met in the Phase 3 trial of Libtayo® (cemiplimab) as monotherapy in first-line non-small cell lung cancer (NSCLC). The Independent Data Monitoring Committee recommended that the trial be stopped early due to highly significant improvement in overall survival. The data from the trial will form the basis of regulatory submissions in the U.S. and EU in the second half of 2020.
- Patient enrollment in the Libtayo Phase 3 first-line NSCLC chemotherapy combination study is expected to be completed in the second half of 2020.
- In May 2020, the Company and Sanofi announced that Libtayo demonstrated clinically-meaningful and durable responses in a pivotal, single-arm, open-label trial in patients with advanced basal cell carcinoma and plan regulatory submissions in 2020.
- The Company now has 6 bispecific antibodies in clinical development for various blood cancers and solid tumors. These include multiple classes of bispecifics including CD3 bispecifics, a CD28 costimulatory bispecific, and other classes of bispecifics.

Praluent® (alirocumab)

- In March 2020, the Company announced that the Phase 3 trial in adult patients with homozygous familial hypercholesterolemia (HoFH) met its primary endpoint and plans to submit an sBLA in mid-2020.

Evinacumab, an antibody to ANGPTL3

- In March 2020, the Company presented positive, detailed results from the Phase 3 trial in patients with HoFH. The Company has also initiated a rolling BLA submission for HoFH and plans to submit an MAA in the EU in the second half of 2020.

Pozelimab, an antibody to C5

- A Phase 2 study in the ultra-rare disease CD55-deficient protein-losing enteropathy was initiated.

REGN-EB3, a multi-antibody therapy to Ebola virus infection

- The FDA accepted for priority review the BLA submission for Ebola, with a target action date of October 25, 2020.

COVID-19 Update

- The Company is advancing REGN-COV2, a novel investigational antibody "cocktail" treatment designed to prevent and treat the SARS-CoV-2 virus. In April, Regeneron moved its leading neutralizing antibodies into pre-clinical and clinical-scale cell production lines and plans to begin clinical studies in June 2020. The Company is working to rapidly scale-up manufacturing, with a goal to have hundreds of thousands of preventative doses available by the end of August 2020.
- In April 2020, the Company provided an update on the adaptively-designed Phase 2/3 U.S. study evaluating Kevzara® (sarilumab) in patients hospitalized with COVID-19 infection. An Independent Data Monitoring Committee recommended continuing the ongoing Phase 3 trial only in the more advanced "critical" group with the 400 mg dose of Kevzara and discontinuing the study in the less advanced "severe" group, based on initial Phase 2 results.
- The Company announced an expanded agreement with the U.S. Department of Health and Human Services (HHS) to fund certain research and development activities related to COVID-19 treatments, including REGN-COV2 and the U.S. Kevzara study.
- The Company continues to monitor the potential impact on product sales. For EYLEA in the United States, there was limited impact on net product sales in the first quarter of 2020. In the month of April 2020, overall U.S. EYLEA demand was lower compared to the same period of 2019 with relative improvement seen by the end of the month. The Company expects to see continued adverse impact on new patient starts for all products while social distancing guidelines remain in place.
- Regeneron maintains adequate market supply for all commercialized products. The Company's raw material supplies and contract manufacturing support have also remained stable. In order to enable the U.S. manufacturing site to produce large-scale quantities of REGN-COV2, the Company is working with the FDA to accelerate licensing of additional commercial products manufactured at its Ireland facility.
- Regeneron expects fully-recruited clinical studies to remain generally on track. The Company has paused new enrollment in certain studies in light of the pandemic and continues to monitor the evolving situation across global trial sites.

Business Development Update

- The Company and Sanofi entered into an agreement, effective April 1, 2020, to restructure its collaboration for Praluent. In the United States, the Company will be solely responsible for the development and commercialization of Praluent and will record net product sales. Sanofi will have sole responsibility for the development and commercialization of Praluent outside the United States, and will pay the Company a 5% royalty on Praluent net product sales.

  In December 2019, the Company and Sanofi also announced their intent to restructure their antibody collaboration for Kevzara. The companies continue to assess potential terms of this restructuring in light of the recently launched clinical programs evaluating Kevzara in patients hospitalized with COVID-19.
- In April 2020, the Company entered into an agreement with Zai Lab Limited to develop and commercialize REGN1979 (bispecific antibody targeting CD20 and CD3) in mainland China, Hong Kong, Taiwan, and Macau. Under the terms of the agreement, Zai is obligated to make a $30 million up-front payment, and we are eligible to receive up to $160 million in additional regulatory and sales milestone payments. The Company will continue to lead global development activities for REGN1979, and Zai will be responsible for funding a portion of the global development costs for certain clinical trials.

First Quarter 2020 Financial Results

Effective January 1, 2020, Regeneron has implemented changes in the presentation of its financial statements related to certain reimbursements and other payments for products developed and commercialized with collaborators. The Company made these changes in presentation to better reflect the nature of the Company's costs incurred and revenues earned pursuant to arrangements with collaborators and to enhance the comparability of Regeneron's financial statements with industry peers. The change in presentation has been applied retrospectively. See Note (4) below for further information.

Revenues

Total revenues increased by 33% to $1.828 billion in the first quarter of 2020, compared to $1.373 billion in the first quarter of 2019.

EYLEA net product sales in the United States were $1.172 billion in the first quarter of 2020, compared to $1.074 billion in the first quarter of 2019. Overall distributor inventory levels for EYLEA in the United States remained within the Company's one-to-two-week targeted range.

Total revenues also include Sanofi and Bayer collaboration revenues[(2)] of $528 million in the first quarter of 2020, compared to $246 million in the first quarter of 2019. Sanofi collaboration revenue in the first quarter of 2020 included the Company's share of profits from collaboration antibodies (Dupixent, Praluent, and Kevzara) of $171 million, while Sanofi collaboration revenue in the first quarter of 2019 included the Company's share of losses from collaboration antibodies of ($28) million. The change in the Company's share of profits (losses) from collaboration antibodies was primarily driven by higher Dupixent profits.

Refer to Table 4 for a summary of collaboration revenue.

Operating Expenses

	GAAP			Non-GAAP[(1)]		
($ in millions)	Q1 2020	Q1 2019	% Change	Q1 2020	Q1 2019	% Change
Research and development (R&D)	$ 584	$ 486	20 %	$ 527	$ 427	23%
Selling, general, and administrative (SG&A)	$ 367	$ 291	26 %	$ 307	$ 242	27%
Cost of goods sold (COGS)	$ 79	$ 71	11 %	$ 70	$ 66	6%
Cost of collaboration and contract manufacturing (COCM)	$ 139	$ 101	38 %	*	*	n/a
Other operating (income) expense, net	$ (40)	$ (57)	(30%)	*	*	n/a

* GAAP and non-GAAP amounts are equivalent as no non-GAAP adjustments have been recorded

- The higher GAAP and non-GAAP R&D expenses in the first quarter of 2020 were principally due to additional costs incurred in connection with our earlier-stage pipeline, higher headcount and headcount-related costs, and an increase in clinical manufacturing activities.
- The higher GAAP and non-GAAP SG&A expenses in the first quarter of 2020 were primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for EYLEA, and higher contributions to independent not-for-profit patient assistance organizations. In addition, GAAP SG&A expenses in the

first quarter of 2020 increased partly due to additional accruals for loss contingencies associated with ongoing litigation.

- The increase in COCM was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent and manufacturing costs in connection with our BARDA Ebola agreement.
- Other operating (income) expense, net, includes recognition of a portion of amounts previously deferred in connection with up-front and development milestone payments, as applicable, received in connection with the Company's collaborative arrangements.

Other Financial Information

GAAP other (expense) income, net, includes the recognition of net losses on equity securities of $57 million in the first quarter of 2020, compared to net gains of $43 million in the first quarter of 2019.

In the first quarter of 2020, the Company's GAAP effective tax rate was 6.6%, compared to 15.6% in the first quarter of 2019. The GAAP effective tax rate for the first quarter of 2020 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation, and, to a lesser extent, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate and federal tax credits for research activities. In the first quarter of 2020, the non-GAAP effective tax rate was 9.5%, compared to 16.0% in the first quarter of 2019.

GAAP net income per diluted share was $5.43 in the first quarter of 2020, compared to GAAP net income per diluted share of $3.99 in the first quarter of 2019. Non-GAAP net income per diluted share was $6.60 in the first quarter of 2020, compared to non-GAAP net income per diluted share of $4.45 in the first quarter of 2019. A reconciliation of the Company's GAAP to non-GAAP results is included in Table 3 of this press release.

During the first quarter of 2020, the Company repurchased 719,167 shares of Common Stock under the Company's share repurchase program and recorded the cost of the shares received, or $273 million, as Treasury Stock. As of March 31, 2020, the Company had $473 million which remained available for share repurchases under the original $1.0 billion program.

The Company generated $528 million in free cash flow for the first quarter of 2020, compared to $823 million for the first quarter of 2019.

***2020 Financial Guidance*[3]**

The Company's full year 2020 financial guidance consists of the following components:

	GAAP	Non-GAAP[1]
R&D	$2.150 billion–$2.310 billion	$1.900 billion–$2.040 billion
SG&A	$1.380 billion–$1.500 billion	$1.190 billion–$1.290 billion
COGS	$350 million–$420 million	$295 million–$355 million
COCM[5]	$600 million–$700 million	*
Other operating (income) expense, net	($175) million–($205) million	*
Capital expenditures	$510 million–$590 million *(previously $520 million–$620 million)*	*
Effective tax rate (ETR)	10–12%	12–14%

* GAAP and non-GAAP amounts are equivalent as no non-GAAP adjustments have been or are expected to be recorded.

A reconciliation of full year 2020 GAAP to Non-GAAP financial guidance is included below:

	Projected Range	
(In millions)	**Low**	**High**
GAAP R&D	$ 2,150	$ 2,310
R&D: Non-cash share-based compensation expense	(250)	(270)
Non-GAAP R&D	$ 1,900	$ 2,040
GAAP SG&A	$ 1,380	$ 1,500
SG&A: Non-cash share-based compensation expense	(160)	(180)
SG&A: Litigation contingencies and other	(30)	(30)
Non-GAAP SG&A	$ 1,190	$ 1,290
GAAP COGS	$ 350	$ 420
COGS: Non-cash share-based compensation expense	(55)	(65)
Non-GAAP COGS	$ 295	$ 355
GAAP ETR	10%	12%
Income tax effect of GAAP to non-GAAP reconciling items	1%	1%
Other	1%	1%
Non-GAAP ETR	12%	14%

(1) This press release uses non-GAAP R&D, non-GAAP SG&A, non-GAAP COGS, non-GAAP effective tax rate, non-GAAP net income, non-GAAP net income per share, and free cash flow, which are financial measures that are not calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP). These non-GAAP financial measures are computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items.

The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate from period to period based on factors that are not within the Company's control (such as the Company's stock price on the dates share-based grants are issued or changes in the fair value of the Company's equity investments) or items that are not associated with normal, recurring operations (such as restructuring-related expenses, including employee separation costs). Management uses these non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of these and other non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the Company's historical GAAP to non-GAAP results is included in Table 3 of this press release.

(2) The Company's collaborators provide it with estimates of the collaborators' respective sales and the Company's share of the profits or losses from commercialization of products for the most recent fiscal quarter. The Company's estimates for such quarter are reconciled to actual results in the subsequent fiscal quarter, and the Company's share of the profit or loss is adjusted on a prospective basis accordingly, if necessary.

(3) The Company's 2020 financial guidance does not assume the completion of any significant business development transactions not completed as of the date of this press release.

(4) Applicable amounts previously reported for the three months ended March 31, 2019 and as of December 31, 2019 have been revised to reflect a change in presentation of cost reimbursements from collaborators who are not deemed to be the Company's customers from collaboration revenue to a reduction of the corresponding operating expense. The Company also changed the presentation of amounts recognized in connection with up-front and development milestone payments received from collaboration revenue to Other operating income, as well as the presentation of the corresponding balance sheet accounts. The revisions were reclassifications only and had no impact on the Company's previously reported GAAP and non-GAAP net income and net income per share. Refer to the Company's Form 10-Q for the quarterly period ended March 31, 2020 (Note 1 of the Notes to Condensed Consolidated Financial Statements) for further details.

(5) Corresponding reimbursements from collaborators and others for manufacturing of commercial supplies is recorded within revenues.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its first quarter 2020 financial and operating results on Tuesday, May 5, 2020, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S.) or (973) 890-8355 (International). A link to the webcast may be accessed from the "Investors and Media" page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for at least 30 days.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases, and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center®, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the Company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron’s business and its employees, collaborators, suppliers, and other third parties on which Regeneron relies, Regeneron’s and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, Regeneron's oncology programs (including its costimulatory bispecific portfolio), Regeneron's COVID-19 antibody program and other earlier-stage programs, and the use of human genetics in

Regeneron's research programs; the likelihood and timing of achieving any of the anticipated milestones described in this press release; unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for Regeneron's Products, including without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, evinacumab, pozelimab, and REGN-EB3; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's Products (such as EYLEA, Dupixent, Libtayo, Praluent, and Kevzara), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and product candidates; competing drugs and product candidates that may be superior to Regeneron's Products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), on the commercial success of Regeneron's Products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and product candidates; coverage and reimbursement determinations by third-party payors, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance, including GAAP and non-GAAP R&D, GAAP and non-GAAP SG&A, GAAP and non-GAAP COGS, COCM, other operating (income) expense, net, capital expenditures, and GAAP and non-GAAP effective tax rate; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to Dupixent and Praluent), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2019 and its Form 10-Q for the quarterly period ended March 31, 2020. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible

on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

Non-GAAP Financial Measures

This press release and/or the financial results attached to this press release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, Regeneron has provided reconciliations of such non-GAAP financial measures.

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Contact Information:

Justin Holko
Investor Relations
914-847-7786
justin.holko@regeneron.com

Hala Mirza
Corporate Communications
914-847-3422
hala.mirza@regeneron.com

TABLE 1

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In millions)

	March 31, 2020	December 31, 2019*
Assets:		
Cash and marketable securities	$ 7,239.8	$ 6,471.1
Accounts receivable - trade, net	2,063.1	2,100.0
Accounts receivable - Sanofi and other	870.1	685.6
Inventories	1,480.9	1,415.5
Property, plant, and equipment, net	2,944.6	2,890.4
Deferred tax assets	771.2	824.2
Other assets	387.8	418.4
Total assets	$ 15,757.5	$ 14,805.2
Liabilities and stockholders' equity:		
Accounts payable, accrued expenses, and other liabilities	$ 2,348.0	$ 2,514.2
Deferred revenue	561.3	487.4
Finance lease liabilities	715.2	713.9
Stockholders' equity	12,133.0	11,089.7
Total liabilities and stockholders' equity	$ 15,757.5	$ 14,805.2

* Certain revisions have been made to the previously reported December 31, 2019 amounts. See note (4) above.

TABLE 2

REGENERON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)
(In millions, except per share data)

	Three Months Ended March 31,	
	2020	**2019***
Revenues:		
Net product sales	$ 1,236.7	$ 1,104.4
Sanofi collaboration revenue	246.9	(18.0)
Bayer collaboration revenue	281.4	264.0
Other revenue	63.2	22.2
	1,828.2	1,372.6
Expenses:		
Research and development	583.9	486.1
Selling, general, and administrative	367.3	291.1
Cost of goods sold	78.8	70.9
Cost of collaboration and contract manufacturing	138.5	101.2
Other operating (income) expense, net	(40.4)	(56.7)
	1,128.1	892.6
Income from operations	700.1	480.0
Other (expense) income, net	(31.5)	66.1
Income before income taxes	668.6	546.1
Income tax expense	44.0	85.0
Net income	$ 624.6	$ 461.1
Net income per share - basic	$ 5.69	$ 4.23
Net income per share - diluted	$ 5.43	$ 3.99
Weighted average shares outstanding - basic	109.8	108.9
Weighted average shares outstanding - diluted	115.1	115.5

* Certain revisions have been made to the previously reported March 31, 2019 amounts. See note (4) above.

TABLE 3

REGENERON PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL INFORMATION (Unaudited)
(In millions, except per share data)

	Three Months Ended March 31,	
	2020	**2019**
GAAP R&D	$ 583.9	$ 486.1
R&D: Non-cash share-based compensation expense	56.7	58.7
Non-GAAP R&D	$ 527.2	$ 427.4
GAAP SG&A	$ 367.3	$ 291.1
SG&A: Non-cash share-based compensation expense	40.3	43.8
SG&A: Litigation contingencies and other	20.2	5.0
Non-GAAP SG&A	$ 306.8	$ 242.3
GAAP COGS	$ 78.8	$ 70.9
COGS: Non-cash share-based compensation expense	8.8	5.4
Non-GAAP COGS	$ 70.0	$ 65.5
GAAP other (expense) income, net	$ (31.5)	$ 66.1
Other income/expense: Losses (gains) on investments in equity securities	56.8	(42.8)
Non-GAAP other (expense) income, net	$ 25.3	$ 23.3
GAAP net income	$ 624.6	$ 461.1
Total of GAAP to non-GAAP reconciling items above	182.8	70.1
Income tax effect of GAAP to non-GAAP reconciling items	(36.8)	(13.5)
Non-GAAP net income	$ 770.6	$ 517.7
Non-GAAP net income per share - basic	$ 7.02	$ 4.75
Non-GAAP net income per share - diluted	$ 6.60	$ 4.45
Shares used in calculating:		
Non-GAAP net income per share - basic	109.8	108.9
Non-GAAP net income per share - diluted	116.7	116.3
Effective tax rate reconciliation:		
GAAP effective tax rate	6.6%	15.6%
Income tax effect of GAAP to non-GAAP reconciling items	2.9%	0.4%
Non-GAAP effective tax rate	9.5%	16.0%
Free cash flow reconciliation:		
Net cash provided by operating activities	$ 698.0	$ 897.0
Capital expenditures	(170.1)	(74.3)
	$ 527.9	$ 822.7

TABLE 4

REGENERON PHARMACEUTICALS, INC.
COLLABORATION REVENUE (Unaudited)
(In millions)

	Three Months Ended March 31,	
	2020	**2019***
Sanofi collaboration revenue:		
Antibody:		
Regeneron's share of profits (losses) in connection with commercialization of antibodies	$ 170.9	$ (27.8)
Reimbursement for manufacturing of commercial supplies	80.1	14.5
Immuno-oncology:		
Regeneron's share of losses in connection with commercialization of Libtayo outside the United States	(6.2)	(4.7)
Reimbursement for manufacturing of commercial supplies	2.1	—
Total Sanofi collaboration revenue	$ 246.9	$ (18.0)
Bayer collaboration revenue:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 253.8	$ 249.3
Reimbursement for manufacturing of commercial supplies	27.6	14.7
Total Bayer collaboration revenue	$ 281.4	$ 264.0

* Certain revisions have been made to the previously reported March 31, 2019 amounts. See note (4) above.

TABLE 5

REGENERON PHARMACEUTICALS, INC.
NET PRODUCT SALES OF REGENERON-DISCOVERED PRODUCTS (Unaudited)
(In millions)

	Three Months Ended March 31,						
	2020			2019			% Change
	U.S.	ROW	Total	U.S.	ROW	Total	(Total Sales)
EYLEA*	$ 1,172.0	$ 681.7	$ 1,853.7	$ 1,074.1	$ 669.4	$ 1,743.5	6%
Libtayo*	61.7	13.1	74.8	26.8	—	26.8	179%
ARCALYST	3.0	—	3.0	3.5	—	3.5	(14%)
Net product sales recorded by Regeneron	$ 1,236.7			$ 1,104.4			
Net product sales recorded by Sanofi:*							
Dupixent	$ 679.0	$ 176.2	$ 855.2	$ 303.0	$ 70.7	$ 373.7	129%
Praluent	$ 35.1	$ 44.7	$ 79.8	$ 22.9	$ 41.0	$ 63.9	25%
Kevzara	$ 35.3	$ 24.8	$ 60.1	$ 20.7	$ 13.0	$ 33.7	78%
ZALTRAP	$ 1.5	$ 26.5	$ 28.0	$ 0.5	$ 24.0	$ 24.5	14%

* Bayer records net product sales of EYLEA outside the United States, and Sanofi records net product sales of Libtayo outside the United States and global net product sales of Dupixent, Kevzara, and ZALTRAP. The Company records its share of profits/losses in connection with (i) sales of EYLEA and Libtayo outside the United States, and (ii) global sales of Dupixent and Kevzara, within collaboration revenue (see Table 4). Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP.

Historically, Sanofi also recorded global net product sales of Praluent and the Company recorded its share of profits/losses in connection with such sales; effective April 1, 2020, the Company and Sanofi entered into an agreement to restructure its collaboration for Praluent; see "Business Development Update" section above for further details.